



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/619,928	07/15/2003	Richard A. Terwilliger	WORLD-01000USB	6815

23910 7590 05/20/2004

FLIESLER MEYER, LLP
FOUR EMBARCADERO CENTER
SUITE 400
SAN FRANCISCO, CA 94111

EXAMINER

VENIAMINOV, NIKITA R

ART UNIT	PAPER NUMBER
----------	--------------

3736

DATE MAILED: 05/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/619,928

Applicant(s)

TERWILLIGER ET AL.

Examiner

Nikita R Veniaminov

Art Unit

3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 7-13 and 18 is/are allowed.
- 6) ☒ Claim(s) 1-6, 14 and 15 is/are rejected.
- 7) ☒ Claim(s) 16 and 17 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>see OA</u> . | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement (IDS) submitted on 11/12/2003 has been considered by the examiner.

Specification

2. The disclosure is objected to because of the following informalities: The phrase "prior to see placement" on page 6, line 10 should read "prior to seed placement". Appropriate correction is required.
3. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code on page 13, line 25. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Claim Objections

4. Claims 1, 5 and 17 are objected to because of the following informalities: Regarding claim 1, line 3 the phrase "in end of plurality" should read "at the end of a plurality"; the phrase "a plurality of treatment strands" in line 4 should read "the plurality of treatment strands". Regarding claim 5, line 2 the phrase "a plurality" should read "the plurality". Regarding claim 17, line 6 the phrase "at least one of" 6 should be deleted. Appropriate corrections are required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. With regard to claim 1, line 5 by using the phrase "wherein at least any of the plurality of treatment strands have a custom distal end spacing" is unclear if "at least" one "of the plurality of treatment strands" or none "of the plurality of treatment strands have a custom distal end spacing".

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

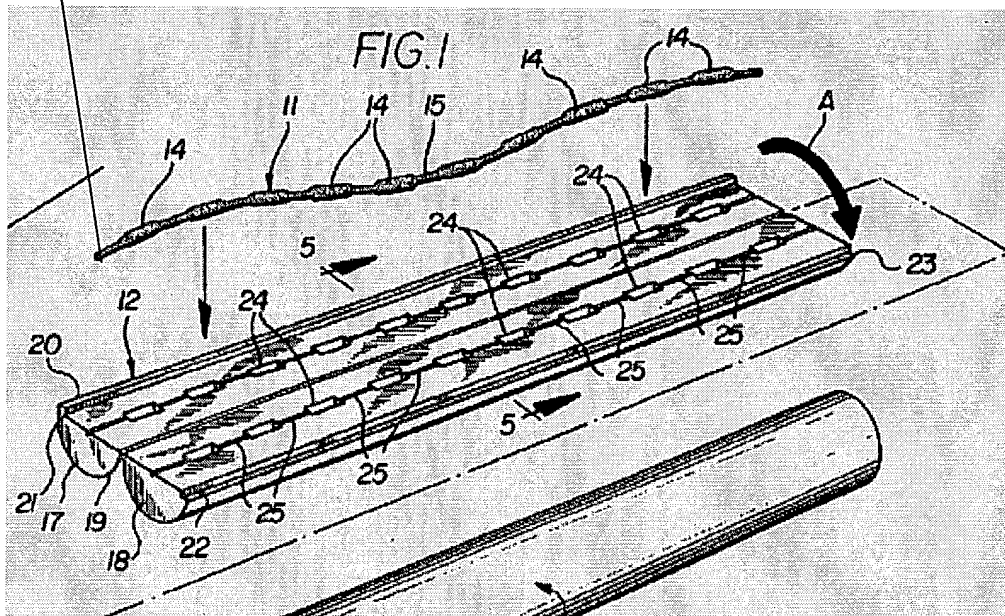
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 1 and 5 are rejected under 35 U.S.C. 102(e) as being anticipated by Lennox (US 6,537,193 B1) cited by Applicant. Lennox ('193) teaches a prescription method of treating tissue comprising the steps of: accepting a tissue treatment plan for the tissue to be treated, which treatment plan specifies a number and spacing of treatment seeds to be provided in a plurality of treatment needles (see column 3, lines 29-57); creating a plurality of treatment strands according to said tissue treatment plan (see column 3, lines 65-68 and column 4, lines 1-14); aligning a plurality of treatment needles in a template (see column 3, lines 46-54 and column 4, lines 5-14). Based on 35 U.S.C. 112, second paragraph rejection in paragraph 6 above, Examiner states that "at least" none "of the plurality of treatment strands have a custom distal end spacing".

9. Claim 14 is rejected under 35 U.S.C. 102(b) as being anticipated by Langton et al. (US 5,460,592) cited by Applicant. Langton et al. ('592) teach a therapeutic device comprising: a seed strand having a length with a distal end [see Figure 1(11)]; a plurality of seeds provided along the length of the strand [see Figure 1(14)]; the seeds being provided at spaced intervals along the length of the strand [see Figure 1(15)]; and a custom end space provided between the seed located adjacent to the distal end and the distal end of the strand (see

Figure 1).



Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lennox (US 6,537,193 B1) cited by Applicant. Lennox ('193) teaches a prescription method of treating tissue as described in paragraph 8 above, but he does not teach a method, wherein all treatment strands are the same length. It would have been obvious to one of ordinary skill in the art at the time of the invention to provide duplicate treatment strands having all same length.

12. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Langton et al. (US 5,460,592) cited by Applicant as applied to claim 14 above. Langton et al. ('592) teach a therapeutic device as described in paragraph 9 above, but they do not teach a plurality of seed strands each with a custom end space. It would have been obvious to one of ordinary skill in the art at the time of the invention to provide duplicate seed strands.

Allowable Subject Matter

13. The following is a statement of reasons for the indication of allowable subject matter: Examiner cited relevant prior art, in particular: Grimm ('583) teaches a method of treatment of prostate cancer using a preloaded needle with radioactive seeds; a template through which the needle is inserted onto a particular, predetermined location within the prostate (see column 6, lines 7-24; Figure 1 and column 3, lines 6-24). Ferguson ('1355) teaches an apparatus and methods for positioning medical material in living tissue using hollow elements that are formed unitarily from a synthetic bioabsorbable material (see abstract; Figure 2 and page 2[0024-0025]). Schmidt ('130) teaches an elongated hollow sleeve; a plurality of axially aligned seeds and spacers loaded into the sleeve [see abstract and Figure 2(18)]. However, none of the prior art, either alone or in combination, teaches or suggests a prescription method of treating tissue comprising a step, wherein at least one treatment strand is created by positioning radioactive seeds in a mold and pouring in a material to mold the radioactive

seeds in place. Further, none of the prior art, either alone or in combination, teaches or suggests a device having a plurality of seed strands, at least two of which have different custom end spacing. Further, none of the prior art, either alone or in combination, teaches or suggests a prescription method of treating tissue which specifies custom end spacing between an end seed in a strand and the end of the strand. Also, none of the prior art, either alone or in combination, teaches or suggests a method of treating a patient with a plurality of treatment strands comprising implanting a remainder of the strands at a respective desired location according to each strand to a depth of a first strand.

14. Claim 16 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

15. Claims 2-4 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

16. Claim 17 would be allowable if rewritten or amended to overcome the objection(s) set forth in this Office action.

17. Claims 7-13 and 18 are allowed.

Conclusion

18. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Grimm ('583); Ferguson ('1355); Schmidt ('106);

Art Unit: 3736

Mercereau et al. ('937); Schmidt ('130) ; Riazat et al. ('504); Spetz ('247);
Horowitz ('745); Luth ('817); Tokita et al. ('109) and Miller ('938).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nikita R Veniaminov whose telephone number is (703) 605-0210. The examiner can normally be reached on Monday-Friday 8 A.M.-5 P.M..


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max F Hindenburg can be reached on (703) 308-3130. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



May 05, 2004.

Nikita R Veniaminov
Examiner
Art Unit 3736



ERIC F. WINAKUR
PRIMARY EXAMINER